

Klarity® Elekta Fraxion and Icon Masks for Radiation Therapy INSTRUCTIONS FOR USE

GENERAL INFORMATION

Klarity Thermoplastic Masks are medical devices used to ensure precise positioning and immobilization of patients undergoing radiation therapy treatment.

PRODUCT DESCRIPTION

The proprietary Klarity thermoplastic material has been specially designed to ensure minimal shrinkage and superior fixation. The result is a mask that molds closely to the patient's contours to provide accurate reproducibility and optimal patient comfort. Klarity masks are available in a variety of sizes and perforation patterns. Please consult www.klaritymedical.com for a complete selection.

MAINTENANCE AND DISPOSAL

Klarity Thermoplastic Masks must be stored in a dry, clean place at a temperature between 50-95 °F (10-35 °C). Dispose of masks with normal facility waste.

INSTRUCTIONS FOR USE

Preparation:

1. Preheat oven or water bath to 165°F (73°C).
2. Fit the baseplate to the treatment table and prepare proper head and neck support.
3. Determine where the holes in the frame fit into the baseplate pins to ensure efficient mask molding.
4. Position the patient on the baseplate.

Heating:

5. Heat mask (two methods):
Convection Oven Method:
 - Remove the mask from the sealed plastic pouch.
 - Place the mask on the rack in the oven.
 - Heat the mask for 3 to 10 minutes, depending on the oven model (do not exceed 30 minutes).
 - The thermoplastic will be translucent when ready.
 - Retrieve the mask from the oven.

Water Bath Method:

- Remove the mask from the sealed plastic pouch.
- Place the mask in the water bath.
- Heat the mask for 1 to 2 minutes (do not exceed 5 minutes).
- The thermoplastic will be translucent when ready.
- Lift the mask from the waterbath and shake off the excess water.

Molding:

6. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
7. Position the mask over the patient's face and place the pre-cut hole at the tip of the nose
8. Pull down on the right and left profiles of the mask, locking them in place.
9. Hold the thermoplastic at the bridge of the nose and pull the top cranial profile down over the patient's head. Lock the cranial profile in place with locking bar or wedge.
10. Position mask under and around the chin as desired.
11. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
12. Leave the mask on the patient until it cools completely, for at least ten minutes. The thermoplastic will shrink slightly during the cooling process.

Removing:

13. Ensure that the mask is rigid and has cooled completely. Removing the mask too soon may result in excess shrinkage and patient discomfort when refitting.
14. Remove the mask from the patient by rotating and pulling up on the pins to release.
15. If desired, treatment portals can be cut into the mask using heavy shears or a cast cutter.

To be used by a qualified medical professional
IFU-M-015



Keep in a
cool and dry
environment



35°C
Store below
35°C (95°F)



EC REP

Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA
The Hague, Netherlands
T: +31645171879 (English)
T: +31626669008 (Dutch)

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, OH 43056
T: 740.788.8107 F: 740-788-8109
info@klaritymedical.com
www.klaritymedical.com